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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/755,164	01/09/2004	Sheng-Ping Zhong	S63.2H-14226-US01	1268
490	7590	06/07/2010		
VIDAS, ARRETT & STEINKRAUS, P.A. SUITE 400, 6640 SHADY OAK ROAD EDEN PRAIRIE, MN 55344			EXAMINER	
			RIDEK, LANCE W	
			ART UNIT	PAPER NUMBER
			1618	
			MAIL DATE	DELIVERY MODE
			06/07/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/755,164	<b>Applicant(s)</b> ZHONG ET AL.
	<b>Examiner</b> LANCE RIDER	<b>Art Unit</b> 1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 29 March 2010.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 31-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-30 and 34-41 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/GS-68)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

## **DETAILED ACTION**

### **Status of the Application**

The remarks and amendments filed on March 29<sup>TH</sup> 2010 are acknowledged.

Claims 1-41 are amended.

### **Response to arguments**

## **Withdrawn Rejections**

Receipt and consideration of Applicants' amended claim set and remarks filed on March 29<sup>TH</sup> 2010 is acknowledged. Rejections and objections not reiterated from previous office actions are hereby withdrawn. The following rejections or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

## **Maintained Rejections**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

**Claims 1-29 and 34-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michal, et al., U.S. Patent 6,287,285 in view of Ronan, et al., U.S. Patent 6,060,534, Brazel, C.S., et al., (Poceedings of the Second Joint EMBS/BMES Conference, 2002) and Weissleder, et al., U.S. Patent 5,514,379.**

**Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Michal, et al., U.S. Patent 6,287,285 in view of Ronan, et al., U.S. Patent 6,060,534, Brazel, C.S., et al., (Poceedings of the Second Joint EMBS/BMES Conference,**

**2002) and Weissleder, et al., U.S. Patent 5,514,379 as applied to claims 1-29, 34-41 above, and further in view of Wang U.S. Patent 6,135,992.**

The rejection of claims 1-30 and 34-41 under U.S.C. 103(a) recited above are maintained for the reasons of record set forth in the office action mailed on February 3<sup>rd</sup> 2010 and for the reasons set forth below.

Applicant's arguments, starting on page 8, of the reply filed on March 29<sup>th</sup> 2010 with respect to the following rejections under 35 USC 103(a) have been fully considered but are not found persuasive:

Applicant argues the following:

1) The stiffness, strength, and ability to adjust the shape of the device of Michal are controlled entirely by the substrate upon which the coating is applied and not by adjustment of the coating, thus the proposed motivation to combine Ronan and Michal is lacking,

2) Brazel's teaching of a higher crosslinking density at the surface of a device would result in diminished softness of the coating and prevent striping of the ionic crosslinking agent which is counter to the intent of Ronan.

3) Weissleder does not cure the deficiencies of Michal, Ronan, and Brazel.

4) Wang does not cure the deficiencies of Michal, Ronan, and Brazel.

In response to applicant's argument 1, the physical properties of the Michal device could be adjusted by another method as suggested by applicant. However, just

because there are other ways to perform this task does not render this combination or the motivation used invalid. Ronan teaches methods for forming shaped hydrogel devices **comprised** of hydrogels, not just those made only from hydrogels. Ronan teaches that the hydrogels can be wrapped around wires and placed over endoscopes. (See column 5, line 49, and column 1, lines 55-60.) Ronans teachings are general methods of how to improve the properties of polymer hydrogels such as those made from alginate. Ways to adjust the stiffness, strength, and shape of these hydrogels are taught. As Michal teaches medical devices comprising alginate hydrogel coatings it logically follows that the methods specifically claimed by Ronan for forming and improving medical devices comprising alginate hydrogels should function on such a device. The reason for combining is based on altering the device of Michal to improve its strength, stiffness, and allow for reshaping after insertion. Ronan teaches that by ionically crosslinking and covalently crosslinking a medical device comprising hydrogels gives the device greater stiffness and strength. This modification of Michal would also function to increase the strength of the coating, and thus the strength of the device. Further the ionic crosslinking could later be stripped allowing for the reshaping of the device. Thus the skilled artisan would have been motivated to make this combination as stated in the previous action.

In response to applicant's arguement 2, Brazel teaches the general principle that surface preferential crosslinking prevents the burst release of drugs. Brazel provides examples in which he uses covalent crosslinking agents but does not require them. Brazel states that crosslinking the surface of the device prevents burst release effects,

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not that any particular type of crosslinking provides this function. By crosslinking the surface of the device taught by Michal with the ionic crosslinking agent calcium, as taught by Ronan and Brazel, one would predict that it would form a stiffer device that would prevent the burst release of drugs from the device. One would also predict that the device would become more pliant over time and reshape itself *in vivo* as the outer ionic crosslinking was removed as taught by Ronan. Providing a higher crosslinking density at the surface using the teachings of Brazel and Ronan would not defeat the stated purpose of Ronan. In fact Ronan states that the devices can be crosslinked to make them stiffer (for insertion or removal), or stripped to make the softer (to provide more comfort). Ronan even teaches stiffening devices by flowing ionic crosslinking agents around them which would result in a higher crosslinking density in the outer surface of the device. (See column 5, lines 9-16.) Brazel merely teaches a specific reason why one would want this density at the outer surface. Thus the combination of Michal, Ronan, and Brazel is still deemed valid.

In response to applicant's arguments 3 and 4, there are no deficiencies found in the teachings of Michal, Ronan, and Brazel. As stated in the previous rejections Wessleider teaches the addition of contrast agents to hydrogel coatings and Wang teaches neurointerventional catheters.

### Conclusion

No claims allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LANCE RIDER whose telephone number is (571)270-1337. The examiner can normally be reached on M-F 11-12 and 1-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571)272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/LANCE RIDER/  
Examiner, Art Unit 1618

/Michael G. Hartley/  
Supervisory Patent Examiner, Art  
Unit 1618